

### REMARKS/ARGUMENTS

Claims 1, 7-8, 11 and 27 stand rejected under Section 103 as unpatentable over Japanese Patent No. 2000-095663 (published March 4, 2000) ("Kondo") by itself or view of Rita Elkins, HAWAIIAN NONI (1998)("Elkins"). Claims 11-12 and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kondo in view of Elkins and U.S. Patent No. 5,503,825 (issued April 2, 1995)("Lane"). Claims 1, 7-8, 11, and 27 stand rejected under 35 U.S.C. 103 (a) as being unpatentable over Tahitian Noni Products (<http://www.noni-now.com>, copyright 1998-2003) (hereinafter 'noni-now') by itself or in view of Kondo. Claims 1, 7-8, 11, 12, 22 and 27 stand rejected under Section 103 as being unpatentable over the Noni-now.com advertisements (<http://www.noni-now.com>)("Advertisements") in view of Pelle et al (6,136,301).

#### Claim Rejections under 35 U.S.C. § 103.

An invention is unpatentable under 35 U.S.C. § 103(a) ("Section 103") "if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains."

To establish a *prima facie* case of obviousness, three criteria must be met. "First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. § 2142.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *In re John R. Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). Any such suggestion must be "found

in the prior art, and not based on applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Indeed, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." M.P.E.P. § 2142.

A "clear and particular" showing of the suggestion to combine is required to support an obviousness rejection under Section 103. *Id.* For the reasons set forth below, Applicant submits that the relevant prior art fails both to teach or suggest all the claim limitations, and to clearly and particularly suggest the combination indicated by the Examiner; thus, Applicant's claims are not obvious in view of the prior art references.

1. Kondo by itself or in view of Elkins

The Examiner points out the limitation 'lip treatment' was not given patentable weight because the recitation occurs in the preamble. Applicant has amended the claims so to give the 'lip treatment' limitation patentable weight.

'Lip treatment' is not taught by Kondo nor the combination of Kondo and Elkins. In fact, Kondo teaches away from using *Morinda citrifolia* as claimed in the present invention. Kondo indicates that vegetable or fruit products alone fail to be effective treatment at all. Kondo, page 2 paragraph 4. Particularly, Kondo indicates that the antibacterial effects of vegetable extracts alone have a low effect. In sharp contrast the present invention claims "*Morinda citrifolia* fruit juice present in an amount between about 0.1-50 percent by weight" as an integral part of the present composition. The present invention claims a composition for lip treatment, which may consist almost entirely of *Morinda citrifolia*. Thus Kondo is inappropriate for a combination reference in as much as it teaches away from the present claims.

Similarly the combination of Kondo and Elkins fails to teach a lip treatment. Elkins details a variety of treatments using *Morinda citrifolia*, but fails to make any mention to lip treatment. As noted by applicant previously, lips have significant physiological differences from skin. Quoting

### **Lips**

The lips (fig. 14) consist of three structures. The outer skin is covered by epidermis, a stratified squamous keratinized epithelium. The vermilion zone, or red area of the lip, is covered by a stratified squamous keratinized epithelium but has no sweat glands or oil glands, which is why we often need to moisten our lips. The junction between the outer skin and the vermilion zone is known as the vermilion border (fig. 14). The internal side of the lip is covered by stratified, non-squamous and non-keratinized epithelium overlying a dense collagenous connective tissue (fig. 14). The lips, which are designed to have maximum flexibility, are tied to the alveolar mucosa via a thin labial frenum that consists of sickle shaped folds of connective tissue. (fig. 15-16)

Source: <http://oralhealth.dent.umich.edu/VODI/html/03-oc/a-anatomy/lips.html>. The significant differences between the epidermis and the vermilion zone necessitate a different composition for treatment. Neither Kondo nor Elkins disclose the 'lip treatment' limitation found in the present invention, and thus the present invention is not obvious in light of Kondo and Elkins.

Furthermore, as stated previously by Applicant, Kondo's reference to 'lip stick' fails to teach a 'lip treatment.' The plain meaning of 'lip stick' does not include a 'lip treatment.' *The American Heritage Dictionary* defines 'lip stick' as, "A small stick of waxy lip coloring enclosed in a cylindrical case. Source: *The American Heritage® Dictionary of the English Language*, Fourth Edition. Even the common understanding of 'lip stick' as make-up does not include 'lip treatment.'

Accordingly, neither Kondo alone, nor in combination with Elkins teaches or suggests every element of the claimed invention as amended. Thus a *prima facie* case for obviousness does not exist and the Applicant respectfully requests the rejection be withdrawn.

Further as Applicant previously stated, Elkins indicates that noni is used as a skin healing agent. Elkins page 30. In particular, Elkins indicates that noni is used as a poultice for wounds, burns and bruises. The content of the Elkin's discussion focuses on the benefits of using a noni poultice for quickly removing dead tissue from burns.

The claim limitation, 'lip treatment' is broader than the application disclosed by Elkins and includes maintenance, and not just remedial acts. The plain meaning of "treatment" includes general maintenance, as evidenced by *Merriam-Webster* definition for "treat: to care for." *Merriam-Webster Online Dictionary*, 2005.

Moreover, Elkins teaches the remedial application to remove dead skin from burns not the topical application of oil from seeds of *Morinda citrifolia* for lip care. Further, Elkins does not disclose the combination of *Morinda citrifolia* seed oil in *Morinda citrifolia* juice in specific quantities as claimed in the present invention. Accordingly, while Kondo and Elkins disclose uses for *Morinda citrifolia*, they fail individually and in combination to teach a 'lip treatment' as claimed in the present application.

2. Kondo by itself or in view of Elkins in further view of Lane.

In as much as Applicant's amendments to the claims obviates the rejection of independent claim 1 under Kondo by itself and Kondo in view of Elkins, Applicant maintains the combination of Kondo in view of Elkins in further view of Lane also fails to establish a *prima facie* case of obviousness because Lane also fails to teach a 'lip treatment.' Thus the prior art references, alone or in combination fail to teach every element of the present invention.

3. noni-now by itself or in view of Kondo

Applicant is unable to find the information cited by the Examiner on <http://www.noni-now.com>, and a copy of Google's cached page is attached. However, Applicant submits that just as Kondo failed to teach a 'lip treatment,' so too does noni-now fail to teach a lip treatment.

Furthermore, the Examiner argues the body balance cream containing *Morinda citrifolia* juice and oil is analogous art because the body non-toxic cream is for external use, and lips are classified as epidermis and dermis. However Applicant points to the definition of lips provided above. (<http://oralhealth.dent.umich.edu/VODI/html/03-oc/a-anatomy/lips.html> (*supra*)). Lips include epithelial tissue which is not skin and is not external. The body cream identified by the Examiner is not appropriate for treating epithelial tissue, which is by definition, a part of the lips and claimed by the present invention.

In addition, utilizing the the noni-now body cream as a 'lip treatment' would change the principle of operation of a reference. As stated by the Examiner, the body cream is for external use. Clearly part of the lips are not external. However, the present invention claims a lip treatment that is suitable for treating the lips.

Thus the Applicant argues the noni-now reference is not appropriate as a prior art reference and thus the combination of Kondo and noni-now do not teach or suggest every element of the present claim and thus the present invention is not obvious over the combination.

Noni-now in view of Pelle et al.

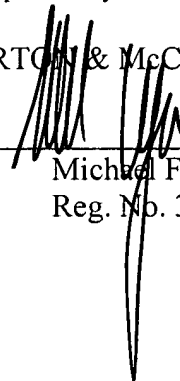
As discussed above, the Examiner relies on noni-now's disclosure of a body balance cream to teach the combination of noni juice and oil. However it is improper to rely on the non-toxic external use cream because the proposed modification would change the principle operation of the reference.

Applicant respectfully requests a timely Notice of Allowance be issued in this case.

Respectfully submitted,

KIRTON & McCONKIE

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